

REMARKS

Applicants appreciate the thorough examination of the present application as evidenced by the final Office Action dated March 2, 2006 (hereinafter, the "Final Action"). Claims 1, 4, 7, 25-27, 31-33, 37 and 47 are pending in the present application upon entry of the present Amendment. Claims 9, 11, 12, 14, 25-27 and 31-46 stand withdrawn from consideration. Claims 1, 4, 7 and 29 are presently under consideration, and these claims stand finally rejected. Applicants provide the remarks below to address the issues presented in the Final Action.

I. Claim Rejections Under 35 U.S.C. § 112

Applicants appreciate the indication that the rejection of Claims 1 and 4 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement has been withdrawn. See Final Action, page 2. However, the written description rejection of Claims 7 and 29 have been maintained. See Final Action, page 2. Further, Claims 1, 4 and 47 are subject to a written description rejection, and more specifically, a rejection on the basis of presenting new matter. See Final Action, page 6.

A. **Rejection of Claims 7 and 29**

The Final Action states that "only the described nucleic acid comprising at least 630 base pairs of sequence immediately upstream of the initiation codon of ORF73 as set forth in SEQ ID NO:1 meet the written description provision." Final Action, page 3.

Applicants have amended Claim 7 to recite as follows:

A recombinant DNA molecule comprising at least one insert that encodes a latency promoter that drives expression of a heterologous gene in human cells, wherein the latency promoter comprises **at least 630 bp** of a nucleic acid sequence immediately upstream of an initiation codon of open reading frame (ORF) 73 of HVS, as set forth in SEQ ID NO:1.

Applicants have amended Claim 29 to recite as follows:

The recombinant DNA molecule according to Claim 7, wherein said latency promoter is encoded by a nucleic acid sequence of **up to a length no greater than 630 bp** of SEQ ID NO: 1.

Accordingly, Applicants respectfully submit that amended Claims 1 and 29 comply with the written description requirement.

B. Claims 1, 4 and 47

The Final Action states that "the Examiner can find no literal support for the specific sequence limitations recited in the claims and it is unclear whether the fragments described, *inter alia*, in the first full paragraph on page 17, comprise the sequence fragments recited in the claims. Therefore, limitation of the promoter to comprising 630 bp of nucleotides 4-633 of SEQ ID NO:1 or nucleotides 4-2003 of SEQ ID NO:1 constitutes impermissible new matter." Final Action, page 7.

The Final Action further states that "implicit support for the limitations might be established by a teaching demonstrating that the PCR primers discussed in the first full paragraph on page 17 would provide the fragments of SEQ ID NO:1 recited in the instant claims. If Applicant can identify such a teaching, this rejection would be overcome." Final Action, page 7. Applicants submit herewith a signed Declaration of Alexander Fred Markham Under 37 C.F.R. § 1.132. In the declaration, Professor Markham declares that the PCR primers discussed in the first full paragraph on page 17 of the present application would provide the fragments of SEQ ID NO:1 recited in the instant claims. Additional support for this assertion is presented in item 3 of the declaration.

Accordingly, Applicants respectfully submit that Claims 1, 4, 29 and 47 comply with the written description requirement, and Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 102

Claims 1, 4, 7, 29 and 47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nicholas et al. (Virol. **188**: 296-310 (1992) (hereinafter, "Nicholas et al.")). See Final Action, page 4.

The Final Action summarizes Applicants' previous remarks of record stating, "Applicant contends that the claims are not anticipated by the art because Nicholas et al. does not discuss a latency promoter or its use to drive expression in human cells as is disclosed in the present application." Final Action, page 4. The Final Action further indicates that Applicants arguments have not been deemed persuasive noting that "[i]t is first noted that claims 7 and 29 do not recite the limitations that Applicant asserts distinguish the instant claims from the prior art." Final Action, page 4.

Applicants have amended independent Claims 1 and 7 to include a recitation directed to expression of the heterologous gene in human cells. Thus, the claims include additional recitations that distinguish the presently claimed invention from the subject matter presented in Nicholas et al. Moreover, Applicants have amended the claim language reciting "capable of driving expression of said heterologous gene" to "drives expression of said heterologous gene."

Accordingly, Applicants respectfully submit that amended Claims 1, 4, 7, 29 and 47 are not anticipated by Nicholas et al., and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

The Examiner is invited and encouraged to contact the undersigned directly, if such contact will expedite the prosecution of the pending claims to issue. In any

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event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



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**CERTIFICATION OF TRANSMISSION
UNDER 37 CFR § 1.8**

I hereby certify that this correspondence is being electronically transmitted to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below:

Signature: Sarah Abraham Date: July 28, 2006
Typed or Printed Name of Person Signing Certificate: Sarah Abraham